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| PPLICATION N                             | O. F | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--|------|-------------|----------------------|-------------------------|-----------------|
| 10/709,194 04/20/2004                    |      | 04/20/2004  | Marlene Bainbridge   | BC-0234-US03            | 3193            |
| 24994                                    | 7590 | 11/02/2004  |                      | EXAMINER                |                 |
| GAMBRO, INC                              |      |             |                      | DEAK, LESLIE R          |                 |
| PATENT DEPARTMENT<br>10810 W COLLINS AVE |      |             |                      | ART UNIT PAPER NUMBER   |                 |
| LAKEWOOD, CO 80215                       |      |             |                      | 3762                    |                 |
|  |      |             |                      | DATE MAILED: 11/02/2004 | 1               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.       | Applicant(s)      |  |  |  |  |   |
|--|-----------------------|-------------------|--|--|--|--|---|
|  | 10/709,194            | BAINBRIDGE ET AL. |  |  |  |  |   |
| Office Action Summary  | Examiner              | Art Unit          |  |  |  |  |   |
|  | Leslie R. Deak        | 3762              |  |  |  |  |   |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |                       |                   |  |  |  |  |   |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                       |                   |  |  |  |  |   |
| Status   |                       | ,                 |  |  |  |  |   |
| 1) Responsive to communication(s) filed on 20 Ap   | oril 2004.            |                   |  |  |  |  |   |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This   | action is non-final.  |                   |  |  |  |  |   |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |                       |                   |  |  |  |  |   |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                       |                   |  |  |  |  |   |
| Disposition of Claims  |                       |                   |  |  |  |  |   |
| 4) Claim(s) <u>1-27</u> is/are pending in the application.   |                       |                   |  |  |  |  |   |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |                       |                   |  |  |  |  |   |
| 5)⊠ Claim(s) <u>26 and 27</u> is/are allowed. 6)⊠ Claim(s) <u>1-25</u> is/are rejected.  |                       |                   |  |  |  |  |   |
|  |                       |                   |  |  |  |  | 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. |
| o) Claim(s) are subject to restriction and/or  | Cicotion requirement. |                   |  |  |  |  |   |
| Application Papers   |                       |                   |  |  |  |  |   |
| 9) The specification is objected to by the Examiner.   |                       |                   |  |  |  |  |   |
| 10)⊠ The drawing(s) filed on <u>20 April 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.   |                       |                   |  |  |  |  |   |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |                       |                   |  |  |  |  |   |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |                       |                   |  |  |  |  |   |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |                       |                   |  |  |  |  |   |
| Priority under 35 U.S.C. § 119   |                       |                   |  |  |  |  |   |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |                       |                   |  |  |  |  |   |
| 1. Certified copies of the priority documents have been received.  |                       |                   |  |  |  |  |   |
| 2. Certified copies of the priority documents have been received in Application No   |                       |                   |  |  |  |  |   |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |                       |                   |  |  |  |  |   |
| application from the International Bureau (PCT Rule 17.2(a)).  |                       |                   |  |  |  |  |   |
| * See the attached detailed Office action for a list of the certified copies not received.   |                       |                   |  |  |  |  |   |
|  |                       |                   |  |  |  |  |   |
| Attachment(s)  |                       |                   |  |  |  |  |   |
| 1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date   |                       |                   |  |  |  |  |   |
| 2) Notice of Draftsperson's Fatent Drawing (Certew (FTO-946)) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) 6) Other:   |                       |                   |  |  |  |  |   |

Application/Control Number: 10/709,194

Art Unit: 3762

## **DETAILED ACTION**

## Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8, 10-14, 17, and 20 of U.S. Patent No. 6,730,055 to Bainbridge et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '055 patent claims the method steps as recited by applicant, but in a slightly different sequence than originally patented. With regard to the various packing factors and AC numbers, it would have been obvious to one having ordinary skill in the art at the time the invention was made to seek the ranges in the instant application, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05.

3. Claims 26-27 are allowed.

4. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the device as claimed. In particular, the prior art fails to suggest a dual stage blood separation chamber with a dam, including a replacement fluid apparatus that delivers replacement fluid, not uncollected blood components, to the patient, along with the other steps and limitations of the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Conclusion

- 5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - a. US 5,720,716

Blakeslee et al

i. Dual stage blood separation apparatus without replacement fluid

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28-Øctober 2004

ANGELA D. SYKES SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

angel. D. Alps